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APPLICATION NO.	FILING DATE	FIRST-NAMED INVENTOR	ATTORNEY-DOCKET NO.	CONFIRMATION NO.
10/018,974	12/26/2001	Kouichirou Hirata	2001_1888A	8006

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/03/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,974

Applicant(s)

HIRATA ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-8,10-12 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,10-12 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry

1. The preliminary amendment filed September 9, 2003 has been entered. Claims 1-3,6-8, 10-11 and 14-18 have been amended. Claims 4, 9 and 13 have been cancelled. Claims 1-3, 5-8, 10-12 and 14-18 are under consideration in this office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

- a) The enablement rejection of claims 1-14 under 35 U.S.C. 112, first paragraph;
- b) The deposit rejection of claims 1-3, 5-8, 10-12 and 14-18 under 35 U.S.C. 112, first paragraph;
- c) The rejection of claims 17-18 under 35 U.S.C. 101;
- c) The rejection of claims 1-13 and 17-18 under 35 U.S.C. 102(b) as being anticipated by Babaahmady et al.

Response to Arguments

3. Applicant's arguments with respect to claims 1-3, 5-8, 10-12 and 14-18 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3, 5-8, 10-12 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Acronyms like S/M must be spelled out when used for the first time in a chain of claims.

5. Dependant claim 16 recites a detection antibody comprising a combination of anti-*S.sobrinus* antibody and an antibody binding to *S. mutans* specifically or a combination of the anti-*S.sobrinus* antibody and an antibody binding to both *S. mutans* and *S. sobrinus*. This is unclear because claim 15 requires that the detection antibody comprise an anti-*S. sobrinus* antibody whose S/M binding selectivity is not less than 100. This limitation thereby excludes an antibody binding to *S. mutans* specifically or a combination of the anti-*S.sobrinus* antibody and an antibody binding to both *S. mutans* and *S. sobrinus* referred to in claim 16. Therefore, it is unclear how applicants are intending to define the recited antibodies. Clarification is required to overcome the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-3, 5-8, 10-12,14 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babaahmady et al., in view of Cabilly et al., (US Patent 4,816,567). Babaahmady et al., teach determining the presence of both *S.mutans* and *S.sobrinus* as a strong corollary with early caries lesions (abstract). The authors made polyclonal anti-*S.sobrinus* serotype d antibody. The high titer-polyclonal mouse antibody was used in conjunction with a rabbit anti-mouse IgG FITC labeled conjugate for use in indirect immunofluorescence labeling (page 52). The samples tested were clinical plaque samples obtained from children (page 52). The anti-*S. sobrinus* antibody showed no-cross reactions and reacted only with homologous strains and none of the other 75 strains tested (page 52-53). Table 1 shows using the anti-*S.sobrinus* antibody had no cross reaction with *S.mutans* serotypes c, e, f and h. The authors also performed experiments to establish the sensitivity of the antibodies when pooled together (page 53). *S.mutans* and *S.sobrinus* were identified together in many samples (page 53).

Therefore, Babaahmady et al., teach a method for detecting *S.sobrinus* comprising providing an antibody, bringing the antibody in contact with the test fluid and assaying the complex, likewise Babaahmady et al., teach judging the degree of infection of dental

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caries and a polyclonal antibody. However, Babaahmady et al., do not teach making the anti-*S.sobrinus* antibody having a higher binding specificity.

Cabilly et al., (US Patent 4,816,567) teach binding specificities are highly refined and can result in a multitude of specificity capabilities being remarkably complex and variable (col. 1 lines 23-26). Antibodies are the foundation of immuno-diagnostic test for many antigenic substances (col. 2 lines 25-30). Altered antibodies techniques are taught as a mechanism to create redesigned antibodies with desired characteristics (col. 7 lines 18-32). Changes in the variable region will improve binding specificity (col. 7 lines 33-35). Genetic manipulation techniques are taught as ways to improve specificity to particular surfaces or allow selective segregation of an antibody (col. 7 lines 42-60). Therefore, Cabilly et al., teach a variety of ways to improve antibody selectivity.

Therefore, it would have been prima facie obvious at the time of applicants' invention to modify the polyclonal anti-*S.sobrinus* antibody of Babaahmady et al., since no more than routine skill would have been required to improve upon the antibody's binding specificity for anti-*S.sobrinus* antibody as compared to its specificity for *S.mutans*. One would have a reasonable expectation of success because Babaahmady et al., already teach the desire to have the antibody distinguish between *S.sobrinus* and *S.mutans*. Only the expected increase in binding specificity would be obtained, since the prior art clearly teaches the desire to have more specific antibodies and the art teaches a variety of ways to make an antibody more specific for the particular antigen.

Therefore a skilled artisan would have had a reasonable expectation of success in improving the specificity of the antibodies.

7. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommer (US Patent 5,569,608) in view of Babaahmady et al., and Cabilly et al., (US Patent 4,816,567).

The claims are drawn to an immunochromatographic strip for detecting S. sobrinus in a test fluid comprising a labeled antibody; a detection antibody; a sample pad; a conjugate pad; and a development membrane.

Sommer (US Patent 5,569,608) teaches immunochromatographic strips which are popular since they apply visual detection schemes (col. 1 lines 5-9). The immunoassay involves the application of a liquid test sample suspected of containing an analyte to be detected to an application zone or sample pad of an immunochromatographic test strip (col. 1 lines 10-13). The strip is comprised of a matrix through which the test fluid and analyte are suspended and/or dissolved and then will flow by capillarity from the application zone to a detection zone where a visual signal or absence of such reveals the presence of the analyte (col. 1 lines 14-16). The analyte can be detected by using a specific binding partner that bears detectable label (col. 9 lines 16-19). The prior art teaches the use of gold sols as labels for antibodies that are detectable without a chemical change (col. 1 lines 58-60). There is a first zone or conjugate pad, which contains mobile specific binding partner for the analyte which bears the detectable label and can react with the analyte to form an analyte/labeled

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binding partner and a second zone or development membrane that contained immobilized substance capable of being bound by the active site of the specific binding partner (col. 2 lines 20-28). Then the developed strip can have its signal determined (col. 2 lines 43-45). See also Figures 1 and 3 for immunochromatographic strips. However Sommer does not teach the use of a polyclonal anti-*S.sobrinus* serotype d antibody.

Babaahmady et al., and Cabilly et al., have been discussed above, and teach the antibody and its use in immunological assays.

Therefore it would have been prima facie obvious at the time of applicants invention to modify the immunochromatographic strip of Sommer to include the polyclonal anti-*S.sobrinus* antibody of Babaahmady et al., and Cabilly et al., since no more than routine skill would have been required to exchange the antibody and use one which preferentially detects *S.sobrinus*. One would have a reasonable expectation of success since one of ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent change. Only the expected labeling effect would have been obtained, since the prior art clearly teaches the detection of *S.sobrinus* and relating it to the determination of the bacteria's presence. Therefore a skilled artisan would have had a reasonable expectation of success in switching the antibodies. The use of alternative and functionally equivalent antibodies would have been desirable to those of ordinary skill in the art based on the availability and known specificity of the polyclonal antibody.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines 
November 24, 2003


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600